The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper ~~146~~ 7

By: Trial Section Merits Panel
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Filed: November 29, 2005

UNITED STATES PATENT AND TRADEMARK OFFICE
(Administrative Patent Judge Carol A. Spiegel)

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

GARY H. RASMUSSON and GLENN F. REYNOLDS
Junior Party,
Application 08/460,296

v.

SMITHKLINE BEECHAM CORPORATION
Senior Party,
U.S. Patent 5,637,310
U.S. Patent 5,496,556
Reissue Application 09/964,383
Reissue Application 09/984,083

Patent Interference 104,646

Before: LEE, SPIEGEL and TIERNEY, Administrative Patent Judges.

SPIEGEL, Administrative Patent Judge.[1]

JUDGMENT - MERITS - Bd.R. 127

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[1] As part of the Board's efforts under the Government Paperwork Elimination Act, signatures on papers originating from the Board are being phased out in favor of a completely electronic record. Consequently, in this case papers originating at the Board will not have signatures. The signature requirements for the parties have not changed. See e.g., 37 C.F.R. § 10.18.

I. Introduction

Pursuant to the 27 June 2005 mandate (Paper 144) of the U.S. Court of Appeals for the Federal Circuit in Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 75 USPQ2d 1297 (Fed. Cir. 2005), this case has been remanded to the Board of Patent Appeals and Interferences ("Board") to make the factual determination of whether the involved claims of the parties are anticipated by European patent application 285383 ("EP 383," Ex 1002) under 35 U.S.C. § 102(b) in light of the court's determination that EP '383 is an enabling reference for purposes of anticipation. We have jurisdiction pursuant to the mandate and 35 U.S.C. § 135.

II. Findings of Fact (FF)

The following findings of fact are supported by a preponderance of the evidence.

1. Following a "MEMORANDUM OPINION and ORDER (Decision on remaining preliminary and miscellaneous motions)" ("the original decision," Paper 122), this interference was redeclared between junior party GARY H. RASMUSSON and GLENN F. REYNOLDS ("**Rasmusson**") and senior party Randall K. Johnson ("**SKB**") (Paper 123).

2. Rasmusson is involved in the interference on the basis of U.S. application 08/460,296 ("the '296 application"), assigned to MERCK & CO., INC.

3. SKB is involved in the interference on the basis of U.S. Patent Nos. 5,637,310 ("the '310 patent") and 5,496,556 ("the '556 patent") and their corresponding reissues applications 09/964,383 ("the '310 reissue application") and 09/984,083 ("the '556 reissue application"), all assigned to SMITHKLINE BEECHAM

CORPORATION.

4. The claims of the parties that correspond to Count 2, the sole count in the interference, are:

Rasmusson '296 application	1-8
SKB '310 patent	1
SKB '310 reissue application	1 and 3
SKB '556 patent	1
SKB '556 reissue application	1-2

[See Papers 1, 38 and 123.]

5. In the original decision, the Board held, in relevant part, that (a) SKB '310 patent claim 1 and SKB '556 patent claim 1, (b) SKB '310 reissue application claim 1, (c) SKB '310 reissue application claim 3 and (d) SKB '556 reissue application claims 1 and 2 were not anticipated by EP '383 because it was a non-enabling reference (Paper 122 at (a) pp. 62-65, (b) pp. 67-68, (c) p. 72 and (d) p. 74).

It is the law of the case that judgment on priority as to Count 2, the sole count in the interference, is awarded against junior party Rasmusson, i.e., GARY H. RASMUSSON and GLENN F. REYNOLDS is not entitled to a patent containing claims 1-8 of application 08/460,296, filed 2 June 1995. See Rasmusson, 413 F.3d at 1326, 75 USPQ2d at 1301. See also Papers 123 and 139.

It is the law of the case that Rasmusson '296 application claims 1-8 have an effective filing date of 2 June 1995. Id.

6. SKB '310 patent claim 1 has an effective filing date of 20 December 1993 (Paper 122, p. 52).

7. SKB '310 reissue application claims 1 and 3 have been accorded an effective

filing date of 27 June 1990 (Paper 123, p. 4).

8. SKB '556 patent claim 1 has been accorded an effective filing date of 27 June 1990 (Paper 123, p. 4).

9. SKB '556 reissue application claims 1 and 2 have been accorded an effective filing date of 27 June 1990 (Paper 123, p. 4).

Other findings of fact follow below.

III. Anticipation

Anticipation requires that the four corners of a single prior art document describe every element of the claimed invention, either expressly or inherently. Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999); In re Paulsen, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994). "[A]nticipation requires that all limitations of the claimed invention are described in a single reference, rather than a single example in the reference." Glaxo Group Ltd. v. Apotex Inc., 376 F.3d 1339, 1348, 71 USPQ2d 1801, 1807 (Fed. Cir. 2004).

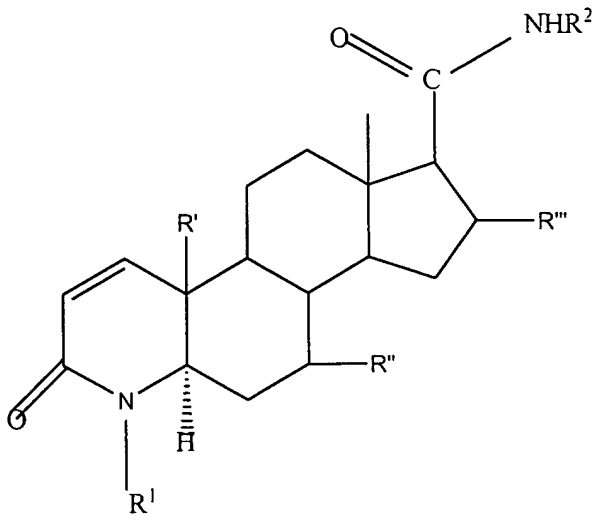
A. EP '383

10. EP '383 was published 5 October 1988 (Ex 1002, p. 1, § 43).

11. EP '383 qualifies as prior art under 35 U.S.C. § 102(b) vis-a-vis (i) Rasmusson '296 application claims 1-8, (ii) SKB '310 patent claim 1, (iii) SKB '310 reissue application claims 1 and 3, (iv) SKB '556 patent claim 1, and (v) SKB '556 reissue application claims 1 and 2.

12. It is the law of the case that EP '383 is an enabling reference for purposes of anticipation. Rasmusson, 413 F.3d at 1320, 75 USPQ2d at 1298.

13. EP '383 describes a method of treating prostatic carcinoma in animals including humans by administering a therapeutic dosage of 17ß-N-monosubstituted-carbamoyl-4-aza-5α-androst-1-en-3-one compounds of formula (I):



wherein

R^1 is hydrogen, methyl or ethyl;

R^2 is a straight or branched chain alkyl of from 1-12 carbons or monocyclic aryl optionally containing 1 or more lower alkyl substituents of from 1-2 carbon atoms and/or 1 or more halogen (Cl, F or Br) substituents;

R' is hydrogen of methyl;

R" is hydrogen or ß-methyl;

R"' is hydrogen, α-methyl or ß methyl

(Ex 1002, p. 2, ll. 6-8; p. 2, l. 50 - p. 3, l. 26; p. 6, ll. 27-28 and 31-33).

14. According to EP '383, 17ß-N-monosubstituted-carbamoyl-4-aza-5α-androst-1-

en-3-one compounds of formula I are testosterone-5α-reductase inhibiting compounds (Ex 1002, p. 2, ll. 6-7 and 46-49; p. 6, ll. 22-24).

15. Testosterone-5α-reductase, steroid 5α-reductase, 3-oxo-5α-steroid Δ^4-reductase (E.C. 1.3.1.22) and 5αR are alternative names for an NADPH-dependent enzyme which catalyzes the conversion of testosterone to dihydrotestosterone ("DHT") (see Paper 122, pp. 4-5).

16. Further according to EP '383, preferred compounds of formula I (FF 13) are compounds wherein R^1 is hydrogen, methyl or ethyl; R^2 is a branched chain alkyl of from 4-8 carbons and R', R" and R"' are all hydrogen (Ex 1002, p. 3, ll. 26-46).[2]

17. EP '383 explicitly lists the following compounds as representative compounds:

17ß-(N-tertbutylcarbamoyl)-4-aza-4-methyl-5-α-androst-1-en-3-one,

17ß-(N-isobutylcarbamoyl)-4-aza-4-methyl-5-α-androst-1-en-3-one,

17ß-(N-tert-octylcarbamoyl)-4-aza-4-methyl-5α-4-methyl-5α-androst-1-en-3-one,

17ß-(N-1,1-diethylbutylcarbamoyl)-4-aza-4-methyl-5-α-androst-1-en-3-one,

17ß-(N-tert-hexylcarbamoyl)-4-aza-4-methyl-5α-androst-1-en-3-one

and the corresponding compounds wherein the 4-methyl substituent is replaced in each of the above compounds by a hydrogen or an ethyl substituent (Ex 1002, p. 3, ll. 47-58).

18. Still further according to EP '383, the 5αR inhibiting compounds described

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[2] Formula II on page 3 of EP '383 depicts the preferred compounds of Formula I. Specifically, R', R" and R"' of Formula I are depicted as hydrogen atoms in Formula II and R^2 of Formula I is designated as R^3 in Formula II.

therein as useful for treating prostatic carcinoma "can be administered in a wide variety of therapeutic dosage forms in conventional vehicles for systemic administration, as, for example, by oral administration in the form of tablets, capsules, solutions, or suspensions, or by intravenous injection" (Ex 1002, p. 6, ll. 31-34).

19. Specifically, EP '383 discloses that daily administration dosage ranges vary

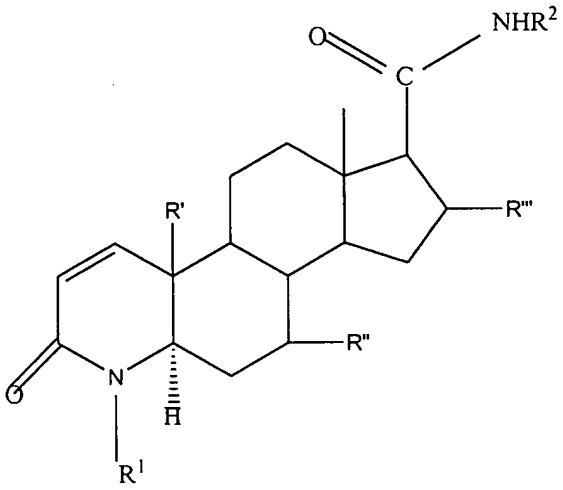
> from 5 to 2,000 mg, preferably from 5 to 200 mg. The compositions are preferably provided in the form of scored tablets containing 5, 10, 25, 50, 100, 150, 250, and 500 milligrams of the active ingredient for the symptomatic adjustment of the dosage to the patient to be treated. An effective amount of the drug is ordinarily supplied at a dosage level of from about 0.1 mg. to about 50 mg./kg. of body weight per day. Preferably the range is from about 0.1 mg. to 7 mg./kgs. of body weight per day and more preferably from about 0.1 mg to about 3 mg/kg of body weight per day. [Ex 1002, p. 6, ll. 34- 40.]

20. It is undisputed that adenocarcinoma comprises 95% of prostate cancers in humans and that the remaining prostate cancers are classified as transitional cell carcinoma, squamous cell carcinoma and undifferentiated carcinoma (Ex 1015, p. 1466, c. 2, ll. 26-28 and p. 1467, ll. 19-45 (Table 32-1)) (see also Paper 68, p. 2 where SKB does not dispute Rasmusson's "Material Facts" ("MFs") 40-42 as set forth in Paper 40, pp. 9-10).

B. Rasmusson '296 application claims 1-8 vis-a-vis EP '383

21. Rasmusson '298 application 1 reads (Paper 3):

A method of treating prostatic carcinoma in animals including humans which comprises administering a therapeutically effective amount of a compound of the formula:



wherein:

R^1 is hydrogen, methyl or ethyl;
R^2 is a branched chain alkyl of from 3-12 carbon atoms;
R' is hydrogen or methyl;
R" is hydrogen or ß-methyl;
R"' is hydrogen, α-methyl or ß-methyl.

22. Rasmusson '296 application claim 2 reads (Paper 3):

A method according to Claim 1 wherein:
R^1 is hydrogen or methyl;
R^2 is branched chain alkyl of from 4-8 carbon atoms;
R', R", R"' are hydrogen.

23. Rasmusson '296 application claim 3 reads (Paper 3):

A method according to Claim 1 wherein the compounds are:
17ß-(N-tertbutylcarbamoyl)-4-aza-4-methyl-5α-androst-1-ene-3-one;
17ß-(N-tertbutylcarbamoyl)-4-aza-5α-androst-1-en-3-one;
17ß-(N-isobutylcarbamoyl)-4-aza-4-methyl-5α-androst-1-en-3-one;

17ß-(N-isobutylcarbamoyl)-4-aza-5α-androst-1-en-3-one;
17ß-(N-tert-octylcarbamoyl)-4-aza-4-methyl-5α-androst-1-en-3-one;
17ß-(N-tert-octylcarbamoyl)-4-aza-5α-androst-1-en-3-one;
17ß-(N-1,1-diethylbutylcarbamoyl)-4-aza-4-methyl-5α-androst-1-en-3-one;
17ß-(N-1,1-diethylbutylcarbamoyl)-4-aza-5α-androst-1-en-3-one;
17ß-(N-tert-hexylcarbamoyl)-4-aza-4-methyl-5α-androst-1-en-3-one;
17ß-(N-tert-hexylcarbamoyl)-4-aza-5α-androst-1-en-3-one; [sic]

24. Rasmusson '296 application claim 3 recites pairs of compounds, i.e., a first compound and its corresponding compound wherein the 4-methyl substitutent of the first compound is replaced by a hydrogen substituent.

25. Rasmusson '296 application claim 4 reads (Paper 3):

> A method according to Claim 3 wherein the compound is 17ß-(N-tertbutylcarbamoyl)-4-aza-5α-androst-1-en-3-one.

EP '383 describes a method of treating prostatic carcinoma in animals, including humans, by administering a therapeutic dosage of 17ß-N-monosubstituted-carbamoyl-4-aza-5α-androst-1-en-3-one compounds of Formula I, which compounds are the same compounds recited in Rasmusson claim 1 (FF 13). EP '383 explicitly describes the compounds recited in Rasmusson claim 2 as preferred 17ß-N-monosubstituted-carbamoyl-4-aza-5α-androst-1-en-1-one compounds of formula I (FF 16). The compounds recited in Rasmusson claims 3 and 4 are explicitly described in EP '383 as examples of the preferred compounds of EP '383 formula I (FF 17).

26. Therefore, Rasmusson '296 application claims 1-4 are anticipated by EP '383.

27. Rasmusson '296 application claim 5 reads (Paper 3) "A method according to Claim 4 wherein the compound is systemically administered."

28. Rasmusson '296 application claim 6 reads (Paper 3) "A method according to Claim 5 wherein the compound is orally administered."

29. Rasmusson '296 application claim 7 reads (Paper 3) "A method according to Claim 6 wherein the compound is administered at a daily dosage of from 5 to 2,000 mg."

30. Rasmusson '296 application claim 8 reads (Paper 3) "A method according to Claim 7 wherein the compound is administered at a daily dosage of from 5 to 200 mg."

EP '383 describes administering the compounds disclosed therein systemically, e.g., by oral administration, (FF 18) in daily dosages of from 5 to 2,000 mg, preferably from 5 to 200 mg (FF 19).

31. Therefore, Rasmusson application claims 5-8 are anticipated by EP '383.

C. SKB '310 patent claim 1 vis-a-vis EP '383

32. SKB '310 patent claim 1 reads (Paper 10):

> A method of treating human prostatic adenocarcinoma which comprises administering to a subject in need thereof an oral dosage unit containing from about 1 mg. to about 500 mg. of a steroid 5-α-reductase inhibiting compound from 1-6 times during a twenty four period.

EP '383 describes a method of treating prostatic carcinoma in humans by administering a therapeutic dosage of a steroid 5-α-reductase inhibiting compound, i.e., a 17ß-N-monosubstituted-carbamoyl-4-aza-5α-androst-1-en-3-one compounds of Formula I (FF 13-15). According to EP '383, the steroid 5-α-reductase inhibiting compound can be administered orally, e.g., in tablets containing 5, 10, 25, 50, 100, 150, 250, and 500 mg of the steroid 5-α-reductase inhibiting compound (FF 18-19). Further according to EP '383, a daily dosage of the steroid 5-α-reductase inhibiting compound ranges from about 5 to 2,000 mg, preferably from 5 to 200 mg (FF 19). Thus, in order

to provide a preferred therapeutic dosage of from 5 to 200 mg per twenty-four hour period of the steroid 5-α-reductase inhibiting compound, a tablet containing the steroid 5-α-reductase inhibiting compound would have to be administered the appropriate number of times per day depending upon the amount of the steroid 5-α-reductase inhibiting compound in the tablet. For example, a tablet containing 100 mg of the steroid 5-α-reductase inhibiting compound would have to be administered once or twice per day to provide the preferred dosage. Thus, EP '383 implicitly describes administering an oral dosage of steroid 5-α-reductase inhibiting compound from 1-6 times during a twenty-four hour period as required by SKB '310 patent claim 1. Finally, one of ordinary skill in the art would immediately envisage the method described in EP '383 as a method treating human prostatic adenocarcinoma since the overwhelming majority, i.e., 95%, of human prostatic carcinomas are adenocarcinomas (FF 20).

33. Therefore, SKB '310 patent claim 1 is anticipated by EP '383.

D. SKB '310 reissue application claims 1 and 3 vis-a-vis EP '383

34. SKB '310 reissue application claim 1 is identical to SKB '310 patent claim 1 and reads as follows (Ex 2049, Bates pp. 9 and 81 ("There has been no change in the claims from claims 1-2 as issued.")[3]):

> A method of treating human prostatic adenocarcinoma which comprises administering to a subject in need thereof an oral dosage unit containing from about 1 mg. to about 500 mg. of a steroid 5-α-reductase

[3] SKB Ex 2049 is a multi-document reissue application of the '310 patent. The individual pages of the documents comprising Ex 2049 have not been sequentially numbered, i.e., Bates numbered, by SKB. In order to maintain a clear record, the individual pages of Ex 2049 have been sequentially numbered in the order in which they were presented. Hence, Ex 2049, Bates p. 9 is columns 7 and 8 of the '310 patent and Ex 2049, Bates p. 81 is page 2 of the "**PRELIMINARY AMENDMENT**" submitted with the reissue application.

inhibiting compound from 1-6 times during a twenty four period.

35. SKB '310 reissue application claim 1 is anticipated by EP '383 for the same reasons as SKB '310 patent claim 1 is anticipated by EP '383 as discussed above in § III.C.

36. Newly added SKB '310 reissue application claim 3 reads (Ex 2053, p. 1):

> A method of treating human prostatic adenocarcinoma which comprises administering to a subject in need thereof an oral dosage unit containing from about 1 mg. to about 500 mg. of 17ß-(N-t-butylcarboxamide)-5-α-androst-1-ene-4-aza-3-one from 1-6 times during a twenty-four hour period.

37. 17ß-(N-t-butylcarboxamide)-5-α-androst-1-ene-4-aza-3-one and 17ß-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-en-3-one are alternative names for the same compound which is also called MK 906, Proscar or Finasteride in the scientific literature (Paper 122, p. 17, FF 12).

SKB '310 reissue application claim 3 differs from SKB '310 reissue claim 1 in requiring the steroid 5-α-reductase inhibiting compound to be 17ß-(N-t-butylcarboxamide)-5-α-androst-1-ene-4-aza-3-one. In addition to reiterating the reasons set forth above explaining why SKB '310 reissue application claim 1 is anticipated by EP '383, we add that EP '383 further explicitly describes 17ß-(N-t-butylcarboxamide)-5-α-androst-1-ene-4-aza-3-one, i.e., 17ß-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-en-3-one, as an example of a preferred steroid 5-α-reductase inhibiting compound according to its Formula I (FF 17).

38. Therefore, SKB '310 reissue application claim 3 is also anticipated by EP '383.

E. SKB '556 patent claim 1 vis-a-vis EP '383

39. SKB '556 patent claim 1 reads (Paper 10):

> A method of treating human prostatic adenocarcinoma which comprises administering in a human subject in need thereof, a dosage unit containing from about 0.1 mg/kg to about 100 mg/kg of a steroid 5-α-reductase inhibiting compound from one to six times daily.

EP '383 describes a method of treating prostatic carcinoma in humans by administering a therapeutic dosage of a steroid 5-α-reductase inhibiting compound, i.e., a 17ß-N-monosubstituted-carbamoyl-4-aza-5α-androst-1-en-3-one compounds of Formula I (FF 15-17). According to EP '383, the steroid 5-α-reductase inhibiting compound can be administered orally, e.g., in tablets containing 5, 10, 25, 50, 100, 150, 250, and 500 mg of the steroid 5-α-reductase inhibiting compound (FF 18-19). Further according to EP '383, an effective dosage of the steroid 5-α-reductase inhibiting compound is ordinarily from about 0.1 mg to about 50 mg/kg of body weight per day (FF 19). Thus, in order to provide an effective dosage of from about 0.1 mg to about 50 mg/kg of body weight per day, a tablet containing the steroid 5-α-reductase inhibiting compound would have to be administered the appropriate number of times per day depending upon the amount of the steroid 5-α-reductase inhibiting compound in the tablet and the body weight of the human being treated. For example, a 150 pound man weighs approximately 68 kg. A dosage from about 0.1 mg to about 50 mg/kg of body weight per day for a body weight of approximately 68 kg is a dosage of from about 6.8 mg to about 3400 mg per day. In order to provide an effective dosage of from about 0.1 mg to about 50 mg/kg of body weight per day for a 150 pound man, a tablet containing 500 mg of the steroid 5-α-reductase inhibiting compound would have to be

administered between about 1 to about 6-7 times per day as required by SKB '556 patent claim 1. Finally, one of ordinary skill in the art would immediately envisage the method described in EP '383 as a method treating human prostatic adenocarcinoma since the overwhelming majority, i.e., 95%, of human prostatic carcinomas are adenocarcinomas (FF 20).

40. Therefore, SKB '556 patent claim 1 is anticipated by EP '383.

F. SKB '556 reissue application claims 1-2 vis-a-vis EP '383

41. SKB '556 reissue application claim 1 is identical to SKB '556 patent claim 1 and reads as follows (Ex 2054, Bates pp. 9 and 149[4]):

> A method of treating human prostatic adenocarcinoma which comprises administering in a human subject in need thereof, a dosage unit containing from about 0.1 mg/kg to about 100 mg/kg of a steroid 5-α-reductase inhibiting compound from one to six times daily.

42. SKB '556 reissue application claim 1 is anticipated by EP '383 for the same reasons as SKB '556 patent claim 1 is anticipated by EP '383 as discussed above in § III.E.

43. New SKB '556 reissue application claim 2 reads (Ex 2054, Bates p. 149):

> A method of treating human prostatic adenocarcinoma which comprises administering in a human subject in need thereof, a dosage unit containing from about 0.1 mg/kg to about 100 mg/kg of 17ß-(N-t-butylcarboxamide)-5-α-androst-1-ene-4-aza-3-one from one to six times daily.

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[4] SKB Ex 2054 is a multi-document reissue application of the '556 patent. The individual pages of the documents comprising Ex 2054 have not been sequentially numbered, i.e., Bates numbered, by SKB. In order to maintain a clear record, the individual pages of Ex 2054 have been sequentially numbered in the order in which they were presented. Hence, Ex 2054, Bates p. 9 is columns 7 and 8 of the '556 patent and Ex 2054, Bates p. 149 is page 1 of the "**PRELIMINARY AMENDMENT**" submitted with the reissue application.

SKB '556 reissue application claim 2 differs from SKB '556 reissue claim 1 in requiring the steroid 5-α-reductase inhibiting compound to be 17ß-(N-t-butylcarboxamide)-5-α-androst-1-ene-4-aza-3-one. In addition to reiterating the reasons set forth above explaining why SKB '556 reissue application claim 1 is anticipated by EP '383, we add that EP '383 further explicitly describes 17ß-(N-t-butylcarboxamide)-5-α-androst-1-ene-4-aza-3-one, i.e., 17ß-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-en-3-one, as an example of a preferred steroid 5-α-reductase inhibiting compound according to its Formula I (FF 17).

44. Therefore, SKB '310 reissue application claim 3 is also anticipated by EP '383.

IV. Order

Based on the foregoing and for the reasons given, the judgment of 8 October 2003 (Paper 139) is modified as follows:

ORDERED that Rasmusson 08/460,296 application claims 1-8 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by European patent application 285383;

FURTHER ORDERED that SKB U.S. Patent 5,637,310 patent claim 1 is unpatentable under 35 U.S.C. § 102(b) as being anticipated by European patent application 285383;

FURTHER ORDERED that SKB U.S. Patent 5,496,556 patent claim 1 is unpatentable under 35 U.S.C. § 102(b) as being anticipated by European patent application 285383;

FURTHER ORDERED that SKB reissue application 09/964,383 claims 1 and 3 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by European patent

application 285383;

FURTHER ORDERED that SKB reissue application 09/984,083 claims 1 and 2 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by European patent application 285383; and

FURTHER ORDERED that a copy of this paper shall be made of record in the files of Rasmusson application 08/460,296; of SKB reissue applications 09/964,383 and 09/984,083; and, of U.S. Patents 5,637,310 and 5,496,556 issued to SKB.

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